AMENDMENTS TO THE CLAIMS

Please amend the claims so that they read as follows:

Claims 1-12 (Canceled)

Claim 13 (Currently Amended): A method for ~~preparing a subcutaneously deliverable biologically active agent~~ subcutaneously administering a biologically active agent, said method comprising:

(a) providing a biologically active agent which can exist in a native conformational state, a denatured conformational state, and an intermediate conformational state which is reversible to said native state and is conformationally between said native and denatured states; and

(b) exposing said biologically active agent to a complexing perturbant to reversibility transform said biologically active agent to said intermediate state and to form a subcutaneously deliverable supramolecular complex, and

(c) subcutaneously administering said supramolecular complex

said perturbant having a molecular weight ranging from about 150 to about 600 daltons, and having at least one hydrophilic moiety and at least one hydrophobic moiety,

said supramolecular complex comprising said perturbant non-covalently complexed with said biologically active agent; and

said biologically active agent not forming a microsphere with said perturbant;

wherein said perturbant is in an amount effective for subcutaneous delivery of said biologically active agent.

Claim 14 (Original): A method as defined in claim 13, wherein said intermediate state has ΔG ranging from about -20 kcal/mole to about 20 kcal/moles relative to said native state.

Claim 15 (Original): A method as defined in claim 13, wherein said biologically active agent is selected from the group consisting of a peptide, a micropolysaccharide, a carbohydrate, a lipid, a pesticide, or any combination of the foregoing.

Claim 16 (Previously Presented): A method as defined in claim 15, wherein said biologically-active agent is selected from the group consisting of human growth hormone, bovine growth hormone, growth hormone-releasing hormone, an interferon, interleukin-II, insulin, heparin, calcitonin, erythropoietin, atrial naturetic factor, an antigen, a monoclonal antibody, somatostatin, adrenocorticotropin, gonadotropin releasing hormone, oxytocin, vasopressin, cromolyn sodium, vancomycin, desferrioxamine (DFO), low molecular weight heparin, antimicrobials, or any combination of any of the foregoing.

Claim 17 (Original): A method as defined in claim 13, wherein said perturbant comprises a proteinoid.

Claim 18 (Original): A method as defined in claim 13, wherein said perturbant is selected from the group consisting of an acylated amino acid and an acylated poly amino acid.

Claim 19 (Original): A method as defined in claim 13, wherein said perturbant is selected from the group consisting of a sulfonated amino acid and a sulfonated poly amino acid.

Claim 20 (Original): A method as defined in claim 13, wherein said perturbant is selected from the group consisting of an acylated aldehyde of an amino acid and an acylated aldehyde of a poly amino acid.

Claim 21 (Original): A method as defined in claim 13, wherein said perturbant is selected from the group consisting of an acylated ketone of an amino acid and an acylated ketone of a poly amino acid.

Claim 22 (Original): A method as defined in claim 13, wherein said perturbant comprises a carboxylic acid having the formula

$$R—CO_2H$$

wherein R is C_1 to C_{24} alkyl, C_2 to C_{24} alkenyl, C_3 to C_{10} cycloalkyl, C_3 to C_{10} cycloalkenyl, phenyl, naphthyl, (C_1 to C_{10} alkyl)phenyl, (C_2 to C_{10} alkenyl)phenyl, (C_1 to C_{10} alkyl) naphthyl, (C_2 to C_{10} alkenyl)naphthyl, phenyl(C_1 to C_{10} alkyl), phenyl(C_2 to C_{10} alkenyl), naphthyl(C_1 to C_{10} alkyl) and naphthyl(C_2 to C_{10} alkenyl);

R being optionally substituted with C_1 to C_{10} alkyl, C_2 to C_{10} alkenyl, C_1 to C_4 alkoxy, -OH, -SH, $-CO_2R^1$, C_3 to C_{10} cycloalkyl, C_3 to C_{10} cycloalkenyl, heterocyclic having 3-10 ring atoms wherein the hetero atom is one or more atoms of N, O, S or any combination thereof, aryl, (C_1 to C_{10} alkyl)aryl, aryl(C_1 to C_{10})alkyl, or any combination thereof;

R being optionally interrupted by oxygen, nitrogen, sulfur, or any combination thereof; and

R^1 is hydrogen, C_1 to C_4 alkyl or C_2 to C_4 alkenyl; or

a salt thereof.

Claim 23 (Currently Amended): A method for subcutaneously administering a biologically active agent ~~subcutaneous delivery composition comprising a supramolecular complex~~ comprising:

(a) providing a biologically active agent in an intermediate conformational state non-covalently complexed with

~~(b)~~ a complexing perturbant having a molecular weight ranging from about 150 to about 600 and having at least one hydrophilic moiety and at least one hydrophobic moiety; and

(b) subcutaneously administering said biologically active agent

wherein said intermediate state is reversible to said native state and is conformationally between a native conformational and a denatured conformational state of said biologically active agent and said composition is not a microsphere; and wherein said perturbant is in an amount effective for subcutaneous delivery of said biologically active agent.

Claim 24 (Currently Amended): ~~A composition as defined in~~ A method as defined in claim 23, wherein said biologically active agent is selected from the group consisting of a peptide, a micropolysaccharide, a carbohydrate, a lipid, a pesticide, or any combination of the foregoing.

Claim 25 (Currently Amended): ~~A composition as defined in~~ A method as defined in claim 24, wherein said biologically-active agent is selected from the group consisting of human growth hormone, bovine growth hormone, growth hormone-releasing hormone, an interferon, interleukin-II, insulin, heparin, calcitonin, erythropoietin, atrial naturetic factor, an antigen, a monoclonal antibody, somatostatin, adrenocorticotropin, gonadotropin releasing hormone, oxytocin,

vasopressin, cromolyn sodium, vancomycin, desferrioxamine (DFO), low molecular weight heparin, antimicrobials, or any combination of any of the foregoing.

Claim 26 (Currently Amended): ~~A composition as defined in~~ A method as defined in claim 23, wherein said perturbant comprises a proteinoid.

Claim 27 (Currently Amended) ~~A composition as defined in~~ A method as defined in claim 23, wherein said perturbant is selected from the group consisting of an acylated amino acid and an acylated poly amino acid.

Claim 28 (Original): A method as defined in claim 46, wherein said perturbant is selected from the group consisting of a sulfonated amino acid and a sulfonated poly amino acid.

Claim 29 (Original): A method as defined in claim 23, wherein said perturbant is selected from the group consisting of an acylated aldehyde of an amino acid and an acylated aldehyde of a poly amino acid.

Claim 30 (Original): A method as defined in claim 23, wherein said perturbant is selected from the group consisting of an acylated ketone of an amino acid and an acylated ketone of a poly amino acid.

Claim 31 (Original): A method as defined in claim 23, wherein said perturbant comprises a carboxylic acid having the formula

$R—CO_2H$

wherein R is C_1 to C_{24} alkyl, C_2 to C_{24} alkenyl, C_3 to C_{10} cycloalkyl, C_3 to C_{10} cycloalkenyl, phenyl, naphthyl, (C_1 to C_{10} alkyl)phenyl, (C_2 to C_{10} alkenyl)phenyl, (C_1 to C_{10} alkyl)naphthyl, (C_2 to C_{10} alkenyl)naphthyl, phenyl(C_1 to C_{10} alkyl), phenyl(C_2 to C_{10} alkenyl), naphthyl(C_1 to C_{10} alkyl) and naphthyl(C_2 to C_{10} alkenyl);

R being optionally substituted with C_1 to C_{10} alkyl, C_2 to C_{10} alkenyl, C_1 to C_4 alkoxy, -OH, -SH, $-CO_2R^1$, C_3 to C_{10} cycloalkyl, C_3 to C_{10} cycloalkenyl, heterocyclic having 3-10 ring atoms wherein the hetero atom is one or more atoms of N, O, S or any combination thereof, aryl, (C_1 to C_{10} alkyl)aryl, aryl(C_1 to C_{10})alkyl, or any combination thereof;

R being optionally interrupted by oxygen, nitrogen, sulfur, or any combination thereof; and

R^1 is hydrogen, C_1 to C_4 alkyl or C_2 to C_4 alkenyl; or

a salt thereof.

Claim 32 (Currently Amended): The method of claim 23, wherein said biologically active agent is introduced to ~~A dosage unit form comprising:~~

~~(A) a composition as defined in claim 23; and~~

~~(B)~~ (a) an excipient,

(b) a diluent,

(c) a disintegrant,

(d) a lubricant,

(e) a plasticizer,

(f) a colorant,

(g) a dosing vehicle, or

(h) any combination thereof.

Claim 33 (Currently Amended): A method for subcutaneously administering an active agent ~~preparing an agent which is capable of being administered by the subcutaneous route to a subject in need of said agent~~, said method comprising:

(a) providing a biologically active agent which can exist in a native conformational state, a denatured conformational state, and an intermediate conformational state which is reversible to said native state and is conformationally between said native and denatured states;

(b) exposing said biologically active agent to a complexing perturbant to reversibly transform said biologically active agent to said intermediate state and to form a subcutaneously administrable supramolecular complex,

said perturbant having a molecular weight between about 150 and about 600 daltons, and having at least one hydrophilic moiety and one hydrophilic moiety,

said supramolecular complex comprising said perturbant non-covalently complexed with said biologically active agent, and

said biologically active agent not forming a microsphere with said perturbant;

wherein said perturbant is in an amount effective for subcutaneous delivery of said biologically active agent; and

(c) preparing a mimetic of said supramolecular complex, and

(d) subcutaneously administering said mimetic.

Claim 34 (Original): A method as defined in claim 33, wherein said biologically active agent comprises a peptide and said mimetic comprises a peptide mimetic.

Claim 35 (Currently Amended): A method for ~~preparing an agent which is capable of being administered~~ subcutaneously administering a biologically active agent, ~~by the subcutaneous route to a subject in need of said agent,~~ said method comprising:

(a) providing a biologically active agent which can exist in a native conformational state, a denatured conformational state, and an intermediate which is reversible to said native state and is conformationally between said native and denatured states;

(b) exposing said biologically active agent to a perturbant to reversibly transform said biologically active agent to said intermediate state, wherein said perturbant is in an amount effective for subcutaneous delivery of said biologically active agent; and

(c) preparing a mimetic of said intermediate state, and

(d) subcutaneously administering said mimetic.

Claim 36 (Original): A method as defined in claim 35, wherein said perturbant comprises a pH changing agent, an ionic strength changing agent, or guanidine hydrochloride.

Claims 37-49 (Canceled)

Claim 50 (Currently Amended): A method for sublingually administering ~~preparing~~ a ~~sublingually administrable~~ biologically active agent, said method comprising:

(a) providing a biologically active agent which can exist in a native conformational state, a denatured conformational state, and an intermediate conformational state which is reversible to said native state and is conformationally between said native and denatured states; and

(b) exposing said biologically active agent to a complexing perturbant to reversibility transform said biologically active agent to said intermediate state and to form a sublingually administrable supramolecular complex, and

(c) sublingually administering said supramolecular complex

said perturbant having a molecular weight ranging from about 150 to about 600 daltons, and having at least one hydrophilic moiety and at least one hydrophobic moiety,

said supramolecular complex comprising said perturbant non-covalently complexed with said biologically active agent; and

said biologically active agent not forming a microsphere with said perturbant;

wherein said perturbant is in an amount effective for sublingual delivery of said biologically active agent.

Claim 51 (Original): A method as defined in claim 50, wherein said intermediate state has ΔG ranging from about -20 kcal/mole to about 20 kcal/moles relative to said native state.

Claim 52 (Original): A method as defined in claim 50, wherein said biologically active agent is selected from the group consisting of a peptide, a micropolysaccharide, a carbohydrate, a lipid, a pesticide, or any combination of the foregoing.

Claim 53 (Previously Presented): A method as defined in claim 52, wherein said biologically-active agent is selected from the group consisting of human growth hormone, bovine growth hormone, growth hormone-releasing hormone, an interferon, interleukin-II, insulin, heparin, calcitonin, erythropoietin, atrial naturetic factor, an antigen, a monoclonal antibody, somatostatin, adrenocorticotropin, gonadotropin releasing hormone, oxytocin, vasopressin, cromolyn sodium, vancomycin, desferrioxamine (DFO), low molecular weight heparin, antimicrobials, or any combination of any of the foregoing.

Claim 54 (Original): A method as defined in claim 50, wherein said perturbant comprises a proteinoid.

Claim 55 (Original): A method as defined in claim 50, wherein said perturbant is selected from the group consisting of an acylated amino acid and an acylated poly amino acid.

Claim 56 (Original): A method as defined in claim 50, wherein said perturbant is selected from the group consisting of a sulfonated amino acid and a sulfonated poly amino acid.

Claim 57 (Original): A method as defined in claim 50, wherein said perturbant is selected from the group consisting of an acylated aldehyde of an amino acid and an acylated aldehyde of a poly amino acid.

Claim 58 (Original): A method as defined in claim 50, wherein said perturbant is selected from the group consisting of an acylated ketone of an amino acid and an acylated ketone of a poly amino acid.

Claim 59 (Original): A method as defined in claim 50, wherein said perturbant comprises a carboxylic acid having the formula

$$R—CO_2H$$

wherein R is C_1 to C_{24} alkyl, C_2 to C_{24} alkenyl, C_3 to C_{10} cycloalkyl, C_3 to C_{10} cycloalkenyl, phenyl, naphthyl, (C_1 to C_{10} alkyl)phenyl, (C_2 to C_{10} alkenyl)phenyl, (C_1 to C_{10} alkyl)naphthyl, (C_2 to C_{10} alkenyl)naphthyl, phenyl(C_1 to C_{10} alkyl), phenyl(C_2 to C_{10} alkenyl), naphthyl(C_1 to C_{10} alkyl) and naphthyl(C_2 to C_{10} alkenyl);

R being optionally substituted with C_1 to C_{10} alkyl, C_2 to C_{10} alkenyl, C_1 to C_4 alkoxy, -OH, -SH, $-CO_2R^1$, C_3 to C_{10} cycloalkyl, C_3 to C_{10} cycloalkenyl, heterocyclic having 3-10 ring atoms wherein the hetero atom is one or more atoms of N, O, S or any combination thereof, aryl, (C_1 to C_{10} alkyl)aryl, aryl(C_1 to C_{10})alkyl, or any combination thereof;

R being optionally interrupted by oxygen, nitrogen, sulfur, or any combination thereof; and

R^1 is hydrogen, C_1 to C_4 alkyl or C_2 to C_4 alkenyl; or

a salt thereof.

Claim 60 (Currently Amended): A <u>method for sublingually administering a biologically active agent</u> ~~sublingual delivery composition comprising a supramolecular complex~~ comprising:

(a) providing a biologically active agent in an intermediate conformational state non-covalently complexed with

~~(b)~~ a complexing perturbant having a molecular weight ranging from about 150 to about 600 and having at least one hydrophilic moiety and at least one hydrophobic moiety;

(b) sublingually administering said biologically active agent

wherein said intermediate state is reversible to said native state and is conformationally between a native conformational and a denatured conformational state of said biologically active agent and said composition is not a microsphere; and wherein said perturbant is in an amount effective for sublingual delivery of said biologically active agent.

Claim 61 (Currently Amended): ~~A composition~~ A method as defined in claim 60, wherein said biologically active agent is selected from the group consisting of a peptide, a micropolysaccharide, a carbohydrate, a lipid, a pesticide, or any combination of the foregoing.

Claim 62 (Currently Amended): ~~A composition~~ A method as defined in claim 61, wherein said biologically-active agent is selected from the group consisting of human growth hormone, bovine growth hormone, growth hormone-releasing hormone, an interferon, interleukin-II, insulin, heparin, calcitonin, erythropoietin, atrial naturetic factor, an antigen, a monoclonal antibody, somatostatin, adrenocorticotropin, gonadotropin releasing hormone, oxytocin, vasopressin, cromolyn sodium, vancomycin, desferrioxamine (DFO), low molecular weight heparin, anitmicrobials, or any combination of any of the foregoing.

Claim 63 (Currently Amended): ~~A composition~~ A method as defined in claim 60, wherein said perturbant comprises a proteinoid.

Claim 64 (Currently Amended): ~~A composition~~ A method as defined in claim 60, wherein said perturbant is selected from the group consisting of an acylated amino acid and an acylated poly amino acid.

Claim 65 (Currently Amended): ~~A composition~~ A method as defined in claim 60, wherein said perturbant is selected from the group consisting of a sulfonated amino acid and a sulfonated poly amino acid.

Claim 66 (Currently Amended): ~~A composition~~ A method as defined in claim 60, wherein said perturbant is selected from the group consisting of an acylated aldehyde of an amino acid and an acylated aldehyde of a poly amino acid.

Claim 67 (Currently Amended): ~~A composition~~ A method as defined in claim 60, wherein said perturbant is selected from the group consisting of an acylated ketone of an amino acid and an acylated ketone of a poly amino acid.

Claim 68 (Currently Amended): ~~A composition~~ A method as defined in claim 60, wherein said perturbant comprises a carboxylic acid having the formula

$$R—CO_2H$$

wherein R is C_1 to C_{24} alkyl, C_2 to C_{24} alkenyl, C_3 to C_{10} cycloalkyl, C_3 to C_{10} cycloalkenyl,

phenyl, naphthyl, (C_1 to C_{10} alkyl)phenyl, (C_2 to C_{10} alkenyl)phenyl, (C_1 to C_{10} alkyl)naphthyl, (C_2 to C_{10} alkenyl)naphthyl, phenyl(C_1 to C_{10} alkyl), phenyl(C_2 to C_{10} alkenyl), naphthyl(C_1 to C_{10} alkyl) and naphthyl(C_2 to C_{10} alkenyl);

R being optionally substituted with C_1 to C_{10} alkyl, C_2 to C_{10} alkenyl, C_1 to C_4 alkoxy, -OH, -SH, $-CO_2R^1$, C_3 to C_{10} cycloalkyl, C_3 to C_{10} cycloalkenyl, heterocyclic having 3-10 ring atoms wherein the hetero atom is one or more atoms of N, O, S or any combination thereof, aryl, (C_1 to C_{10} alkyl)aryl, aryl(C_1 to C_{10})alkyl, or any combination thereof;

R being optionally interrupted by oxygen, nitrogen, sulfur, or any combination thereof; and

R^1 is hydrogen, C_1 to C_4 alkyl or C_2 to C_4 alkenyl; or

a salt thereof.

Claim 69 (Currently Amended): ~~A dosage unit form comprising~~ A method as defined in claim 60, wherein said biologically active agent is introduced to:

~~(A) a composition as defined in claim 60; and~~

~~(B)~~ (a) an excipient,

(b) a diluent,

(c) a disintegrant,

(d) a lubricant,

(e) a plasticizer,

(f) a colorant,

(g) a dosing vehicle, or

(h) any combination thereof.

Claim 70(Currently Amended): A method for ~~preparing~~ sublingually administering an agent ~~which is capable of being administered by the sublingual route~~ to a subject in need of said agent, said method comprising:

(a) providing a biologically active agent which can exist in a native conformational state, a denatured conformational state, and an intermediate conformational state which is reversible to said native state and is conformationally between said native and denatured states;

(b) exposing said biologically active agent to a complexing perturbant to reversibly transform said biologically active agent to said intermediate state and to form a sublingually administrable supramolecular complex,

said perturbant having a molecular weight between about 150 and about 600 daltons, and having at least one hydrophilic moiety and one hydrophilic moiety,

said supramolecular complex comprising said perturbant non-covalently complexed with said biologically active agent, and

said biologically active agent not forming a microsphere with said perturbant;

wherein said perturbant is in an amount effective for sublingual delivery of said biologically active agent; and

(c) preparing a mimetic of said supramolecular complex, and

(d) sublingually administering said mimetic.

Claim 71 (Original): A method as defined in claim 70, wherein said biologically active agent comprises a peptide and said mimetic comprises a peptide mimetic.

Claim 72(Currently Amended): A method for ~~preparing an agent which is capable of being administered by the sublingual route~~ sublingually administering a biologically active agent to a subject in need of said agent, said method comprising:

(a) providing a biologically active agent which can exist in a native conformational state, a denatured conformational state, and an intermediate which is reversible to said native state and is conformationally between said native and denatured states;

(b) exposing said biologically active agent to a perturbant to reversibly transform said biologically active agent to said intermediate state, wherein said perturbant is in an amount effective for sublingual delivery of said biologically active agent; and

(c) preparing a mimetic of said intermediate state, and

(d) sublingually administering said mimetic.

Claim 73 (Original): A method as defined in claim 72, wherein said perturbant comprises a pH changing agent, an ionic strength changing agent, or guanidine hydrochloride.

Claims 74-86 (Canceled)

Claim 87 (Currently Amended): A method for ~~preparing an~~ intranasally ~~administrable~~ administering a biologically active agent, said method comprising:

(a) providing a biologically active agent which can exist in a native conformational state, a denatured conformational state, and an intermediate conformational state which is reversible to said native state and is conformationally between said native and denatured states; and

(b) exposing said biologically active agent to a complexing perturbant to reversibility transform said biologically active agent to said intermediate state and to form an intranasally administrable supramolecular complex, and

(c) intranasally administering said supramolecular complex,

said perturbant having a molecular weight ranging from about 150 to about 600 daltons, and having at least one hydrophilic moiety and at least one hydrophobic moiety,

said supramolecular complex comprising said perturbant non-covalently complexed with said biologically active agent; and

said biologically active agent not forming a microsphere with said perturbant;

wherein said perturbant is in an amount effective for intranasal delivery of said biologically active agent.

Claim 88 (Original): A method as defined in claim 87, wherein said intermediate state has ΔG ranging from about -20 kcal/mole to about 20 kcal/moles relative to said native state.

Claim 89 (Original): A method as defined in claim 87, wherein said biologically active agent is selected from the group consisting of a peptide, a micropolysaccharide, a carbohydrate, a lipid, a pesticide, or any combination of the foregoing.

Claim 90 (Previously Presented): A method as defined in claim 89, wherein said biologically-active agent is selected from the group consisting of human growth hormone, bovine growth hormone, growth hormone-releasing hormone, an interferon, interleukin-II, insulin, heparin,

calcitonin, erythropoietin, atrial naturetic factor, an antigen, a monoclonal antibody, somatostatin, adrenocorticotropin, gonadotropin releasing hormone, oxytocin, vasopressin, cromolyn sodium, vancomycin, desferrioxamine (DFO), low molecular weight heparin, antimicrobials, or any combination of any of the foregoing.

Claim 91 (Original): A method as defined in claim 87, wherein said perturbant comprises a proteinoid.

Claim 92 (Original): A method as defined in claim 87, wherein said perturbant is selected from the group consisting of an acylated amino acid and an acylated poly amino acid.

Claim 93 (Original): A method as defined in claim 87, wherein said perturbant is selected from the group consisting of a sulfonated amino acid and a sulfonated poly amino acid.

Claim 94 (Original): A method as defined in claim 87, wherein said perturbant is selected from the group consisting of an acylated aldehyde of an amino acid and an acylated aldehyde of a poly amino acid.

Claim 95 (Original): A method as defined in claim 87, wherein said perturbant is selected from the group consisting of an acylated ketone of an amino acid and an acylated ketone of a poly amino acid.

Claim 96 (Original): A method as defined in claim 87, wherein said perturbant comprises a carboxylic acid having the formula

$$R—CO_2H$$

wherein R is C_1 to C_{24} alkyl, C_2 to C_{24} alkenyl, C_3 to C_{10} cycloalkyl, C_3 to C_{10} cycloalkenyl, phenyl, naphthyl, (C_1 to C_{10} alkyl)phenyl, (C_2 to C_{10} alkenyl)phenyl, (C_1 to C_{10} alkyl)naphthyl, (C_2 to C_{10} alkenyl)naphthyl, phenyl(C_1 to C_{10} alkyl), phenyl(C_2 to C_{10} alkenyl), naphthyl(C_1 to C_{10} alkyl) and naphthyl(C_2 to C_{10} alkenyl);

R being optionally substituted with C_1 to C_{10} alkyl, C_2 to C_{10} alkenyl, C_1 to C_4 alkoxy, -OH, -SH, $-CO_2R^1$, C_3 to C_{10} cycloalkyl, C_3 to C_{10} cycloalkenyl, heterocyclic having 3-10 ring atoms wherein the hetero atom is one or more atoms of N, O, S or any combination thereof, aryl, (C_1 to C_{10} alkyl)aryl, aryl(C_1 to C_{10})alkyl, or any combination thereof;

R being optionally interrupted by oxygen, nitrogen, sulfur, or any combination thereof; and

R^1 is hydrogen, C_1 to C_4 alkyl or C_2 to C_4 alkenyl; or

a salt thereof.

Claim 97 (Currently Amended): ~~An~~ A method for intranasally administering a biologically active agent ~~intranasal delivery composition comprising a supramolecular complex~~ comprising:

(a) providing a biologically active agent in an intermediate conformational state non-covalently complexed with

~~(b)~~ a complexing perturbant having a molecular weight ranging from about 150 to about 600 and having at least one hydrophilic moiety and at least one hydrophobic moiety; and

(b) intranasally administering said biologially active agent

wherein said intermediate state is reversible to said native state and is conformationally between a native conformational and a denatured conformational state of said biologically active agent and said composition is not a microsphere; and wherein said perturbant is in an amount effective for intranasal delivery of said biologically active agent.

Claim 98 (Currently Amended): ~~A composition~~ A method as defined in claim 97, wherein said biologically active agent is selected from the group consisting of a peptide, a micropolysaccharide, a carbohydrate, a lipid, a pesticide, or any combination of the foregoing.

Claim 99 (Currently Amended): ~~A composition~~ A method as defined in claim 98, wherein said biologically-active agent is selected from the group consisting of human growth hormone, bovine growth hormone, growth hormone-releasing hormone, an interferon, interleukin-II, insulin, heparin, calcitonin, erythropoietin, atrial naturetic factor, an antigen, a monoclonal antibody, somatostatin, adrenocorticotropin, gonadotropin releasing hormone, oxytocin, vasopressin, cromolyn sodium, vancomycin, desferrioxamine (DFO), low molecular weight heparin, antimicrobials, or any combination of any of the foregoing.

Claim 100 (Currently Amended): ~~A composition~~ A method as defined in claim 97, wherein said perturbant comprises a proteinoid.

Claim 101 (Currently Amended): ~~A composition~~ A method as defined in claim 97, wherein said perturbant is selected from the group consisting of an acylated amino acid and an acylated poly amino acid.

Claim 102 (Currently Amended): ~~A composition~~ A method as defined in claim 97, wherein said perturbant is selected from the group consisting of a sulfonated amino acid and a sulfonated poly amino acid.

Claim 103 (Currently Amended): ~~A composition~~ A method as defined in claim 97, wherein said perturbant is selected from the group consisting of an acylated aldehyde of an amino acid and an acylated aldehyde of a poly amino acid.

Claim 104 (Currently Amended): ~~A composition~~ A method as defined in claim 97, wherein said perturbant is selected from the group consisting of an acylated ketone of an amino acid and an acylated ketone of a poly amino acid.

Claim 105 (Currently Amended): ~~A composition~~ A method as defined in claim 97, wherein said perturbant comprises a carboxylic acid having the formula

$$R—CO_2H$$

wherein R is C_1 to C_{24} alkyl, C_2 to C_{24} alkenyl, C_3 to C_{10} cycloalkyl, C_3 to C_{10} cycloalkenyl, phenyl, naphthyl, (C_1 to C_{10} alkyl)phenyl, (C_2 to C_{10} alkenyl)phenyl, (C_1 to C_{10} alkyl)naphthyl, (C_2 to C_{10} alkenyl)naphthyl, phenyl(C_1 to C_{10} alkyl), phenyl(C_2 to C_{10} alkenyl), naphthyl(C_1 to C_{10} alkyl) and naphthyl(C_2 to C_{10} alkenyl);

R being optionally substituted with C_1 to C_{10} alkyl, C_2 to C_{10} alkenyl, C_1 to C_4 alkoxy, -OH, -SH, $-CO_2R^1$, C_3 to C_{10} cycloalkyl, C_3 to C_{10} cycloalkenyl, heterocyclic having 3-10 ring atoms wherein the hetero atom is one or more atoms of N, O, S or any combination thereof, aryl, (C_1 to C_{10} alkyl)aryl, aryl(C_1 to C_{10})alkyl, or any combination thereof;

R being optionally interrupted by oxygen, nitrogen, sulfur, or any combination thereof; and

R^1 is hydrogen, C_1 to C_4 alkyl or C_2 to C_4 alkenyl; or

a salt thereof.

Claim 106 (Currently Amended): ~~A dosage unit form comprising~~ A method as defined in claim 93, wherein said biologically active is introduced to ~~further comprises~~:

~~(A) a composition as defined in claim 97; and~~

~~(B)~~ (a) an excipient,

(b) a diluent,

(c) a disintegrant,

(d) a lubricant,

(e) a plasticizer,

(f) a colorant,

(g) a dosing vehicle, or

(h) any combination thereof.

Claim 107(Currently Amended): A method for ~~preparing an agent which is capable of being administered by the intranasal route~~ intranasally administering a biologically active agent

to a subject in need of said agent, said method comprising:

(a) providing a biologically active agent which can exist in a native conformational state, a denatured conformational state, and an intermediate conformational state which is reversible to said native state and is conformationally between said native and denatured states;

(b) exposing said biologically active agent to a complexing perturbant to reversibly transform said biologically active agent to said intermediate state and to form an intranasally administrable supramolecular complex,

said perturbant having a molecular weight between about 150 and about 600 daltons, and having at least one hydrophilic moiety and one hydrophilic moiety,

said supramolecular complex comprising said perturbant non-covalently complexed with said biologically active agent, and

said biologically active agent not forming a microsphere with said perturbant;

wherein said perturbant is in an amount effective for intranasal delivery of said biologically active agent; and

(c) preparing a mimetic of said supramolecular complex, and

(d) intranasally administering said supramolecular complex.

Claim 108 (Original): A method as defined in claim 107, wherein said biologically active agent comprises a peptide and said mimetic comprises a peptide mimetic.

Claim 109(Currently Amended): A method for ~~preparing an~~ intranasally administering a biollogically active agent ~~which is capable of being administered by the intranasal route~~ to a subject in need of said agent, said method comprising:

(a) providing a biologically active agent which can exist in a native conformational state, a denatured conformational state, and an intermediate which is reversible to said native state and is conformationally between said native and denatured states;

(b) exposing said biologically active agent to a perturbant to reversibly transform said biologically active agent to said intermediate state, wherein said perturbant is in an amount effective for intranasal delivery of said biologically active agent; and

(c) preparing a mimetic of said intermediate state, and

(d) intranasally administering said biologically active agent.

Claim 110 (Original): A method as defined in claim 109, wherein said perturbant comprises a pH changing agent, an ionic strength changing agent, or guanidine hydrochloride.

Claim 111 (Canceled).

Claim 112 (Previously Presented): The method of claim 128, wherein the biologically active agent is human growth hormone.

Claim 113 (Previously Presented): The method of claim 128, wherein the biologically active agent is growth-hormone releasing hormone.

Claim 114 (Previously Presented): The method of claim 128, wherein the biologically active agent is insulin.

Claim 115 (Previously Presented): The method of claim 128, wherein the biologically active agent is heparin.

Claim 116 (Previously Presented): The method of claim 128, wherein the biologically active agent is low molecular weight heparin.

Claim 117 (Previously Presented): The method of claim 128, wherein the biologically active agent is calcitonin.

Claim 118 (Previously Presented): The method of claim 128, wherein the biologically active agent is cromolyn sodium.

Claim 119 (Previously Presented): The method of claim 128, wherein the biologically active agent is an antimicrobial.

Claim 120 (Currently Amended): The ~~composition~~ method of claim 129, wherein the biologically active agent is human growth hormone.

Claim 121 (Currently Amended): The ~~composition~~ method of claim 129, wherein the biologically active agent is growth-hormone releasing hormone.

Claim 122 (Currently Amended): The ~~composition~~ method of claim 129, wherein the biologically active agent is insulin.

Claim 123 (Currently Amended): The ~~composition~~ method of claim 129, wherein the biologically active agent is heparin.

Claim 124 (Currently Amended): The ~~composition~~ method of claim 129, wherein the biologically active agent is low molecular weight heparin.

Claim 125 (Currently Amended): The ~~composition~~ method of claim 129, wherein the biologically active agent is calcitonin.

Claim 126 (Currently Amended): The ~~composition~~ method of claim 129, wherein the biologically active agent is cromolyn sodium.

Claim 127 (Currently Amended): The ~~composition~~ method of claim 129, wherein the biologically active agent is an antimicrobial.

Claim 128 (Previously Presented): A method as defined in claim 55, wherein said perturbant is an acylated amino acid.

Claim 129 (Currently Amended): A ~~composition~~ method as defined in claim 64, wherein said perturbant is an acylated amino acid.

Claim 130 (Previously Presented): A method as defined in claim 128, wherein the biologically active agent is a peptide.

Claim 131 (Previously Presented): A method as defined in claim 130, wherein the biologically active agent is an interferon.

Claim 132 (Previously Presented): A method as defined in claim 130, wherein the biologically active agent is erythropoietin.

Claim 133 (Previously Presented): A method as defined in claim 130, wherein the biologically active agent is an antigen.

Claim 134 (Currently Amended): A ~~composition~~ method as defined in claim 129, wherein the biologically active agent is a peptide.

Claim 135 (Currently Amended): A ~~composition~~ method as defined in claim 134, wherein the biologically active agent is an interferon.

Claim 136 (Currently Amended): A ~~composition~~ method as defined in claim 134, wherein the biologically active agent is erythropoietin.

Claim 137 (Currently Amended): A ~~composition~~ method as defined in claim 134, wherein the biologically active agent is an antigen.

Claim 138 (Currently Amended): A ~~composition~~ method as defined in claim 18, wherein said perturbant is an acylated amino acid.

Claim 139 (Previously Presented): The method of claim 138, wherein the biologically active agent is human growth hormone.

Claim 140 (Currently Amended): The method of claim 138, wherein the biologically active agent is growth-hormone releasing hormone.

Claim 141 (Previously Presented): The method of claim 138, wherein the biologically active agent is insulin.

Claim 142 (Previously Presented): The method of claim 138, wherein the biologically active agent is heparin.

Claim 143 (Previously Presented): The method of claim 138, wherein the biologically active agent is low molecular weight heparin.

Claim 144 (Previously Presented): The method of claim 138, wherein the biologically active agent is calcitonin.

Claim 145 (Previously Presented): The method of claim 138, wherein the biologically active agent is cromolyn sodium.

Claim 146 (Previously Presented): The method of claim 138, wherein the biologically active agent is an antimicrobial.

Claim 147 (Previously Presented): A method as defined in claim 138, wherein the biologically active agent is a peptide.

Claim 148 (Previously Presented): A method as defined in claim 147, wherein the biologically active agent is an interferon.

Claim 149 (Previously Presented): A method as defined in claim 147, wherein the biologically active agent is erythropoietin.

Claim 150 (Previously Presented): A method as defined in claim 147, wherein the biologically active agent is an antigen.

Claim 151 (Currently Amended): A ~~composition~~ method as defined in claim 27, wherein said perturbant is an acylated amino acid.

Claim 152 (Currently Amended): The ~~composition~~ method of claim 151, wherein the biologically active agent is human growth hormone.

Claim 153 (Currently Amended): The ~~composition~~ method of claim 151, wherein the biologically active agent is growth-hormone releasing hormone.

Claim 154 (Currently Amended): The ~~composition~~ method of claim 151, wherein the biologically active agent is insulin.

Claim 155 (Currently Amended): The ~~composition~~ method of claim 151, wherein the biologically active agent is heparin.

Claim 156 (Currently Amended): The ~~composition~~ method of claim 151, wherein the biologically active agent is low molecular weight heparin.

Claim 157 (Currently Amended): The ~~composition~~ method of claim 151, wherein the biologically active agent is calcitonin.

Claim 158 (Currently Amended): The ~~composition~~ method of claim 151, wherein the biologically active agent is cromolyn sodium.

Claim 159 (Currently Amended): The ~~composition~~ method of claim 151, wherein the biologically active agent is an antimicrobial.

Claim 160 (Currently Amended): A ~~composition~~ method as defined in claim 151, wherein the biologically active agent is a peptide.

Claim 161 (Currently Amended): A ~~composition~~ method as defined in claim 160, wherein the biologically active agent is an interferon.

Claim 162 (Currently Amended): A ~~composition~~ method as defined in claim 160, wherein the biologically active agent is erythropoietin.

Claim 163 (Currently Amended): A ~~composition~~ method as defined in claim 160, wherein the biologically active agent is an antigen.

Claim 164 (Previously Presented): A method as defined in claim 92, wherein said perturbant is an acylated amino acid.

Claim 165 (Previously Presented): The method of claim 164, wherein the biologically active agent is human growth hormone.

Claim 166 (Previously Presented): The method of claim 164, wherein the biologically active agent is growth-hormone releasing hormone.

Claim 167 (Previously Presented): The method of claim 164, wherein the biologically active agent is insulin.

Claim 168 (Previously Presented): The method of claim 164, wherein the biologically active agent is heparin.

Claim 169 (Previously Presented): The method of claim 164, wherein the biologically active agent is low molecular weight heparin.

Claim 170 (Previously Presented): The method of claim 164, wherein the biologically active agent is calcitonin.

Claim 171 (Previously Presented): The method of claim 164, wherein the biologically active agent is cromolyn sodium.

Claim 172 (Previously Presented): The method of claim 164, wherein the biologically active agent is an antimicrobial.

Claim 173 (Previously Presented): A method as defined in claim 164, wherein the biologically active agent is a peptide.

Claim 174 (Previously Presented): A method as defined in claim 173, wherein the biologically active agent is an interferon.

Claim 175 (Previously Presented): A method as defined in claim 173, wherein the biologically active agent is erythropoietin.

Claim 176 (Previously Presented): A method as defined in claim 173, wherein the biologically active agent is an antigen.

Claim 177 (Currently Amended): A ~~composition~~ method as defined in claim 101, wherein said perturbant is an acylated amino acid.

Claim 178 (Currently Amended): The ~~composition~~ method of claim 177, wherein the biologically active agent is human growth hormone.

Claim 179 (Currently Amended): The ~~composition~~ method of claim 177, wherein the biologically active agent is growth-hormone releasing hormone.

Claim 180 (Currently Amended): The ~~composition~~ method of claim 177, wherein the biologically active agent is insulin.

Claim 181 (Currently Amended): The ~~composition~~ method of claim 177, wherein the biologically active agent is heparin.

Claim 182 (Currently Amended): The ~~composition~~ method of claim 177, wherein the biologically active agent is low molecular weight heparin.

Claim 183 (Currently Amended): The ~~composition~~ method of claim 177, wherein the biologically active agent is calcitonin.

Claim 184 (Currently Amended): The ~~composition~~ method of claim 177, wherein the biologically active agent is cromolyn sodium.

Claim 185 (Currently Amended): The ~~composition~~ method of claim 177, wherein the biologically active agent is an antimicrobial.

Claim 186 (Currently Amended): A ~~composition~~ method as defined in claim 177, wherein the biologically active agent is a peptide.

Claim 187 (Currently Amended): A ~~composition~~ method as defined in claim 186, wherein the biologically active agent is an interferon.

Claim 188 (Currently Amended): A ~~composition~~ method as defined in claim 186, wherein the biologically active agent is erythropoietin.

Claim 189 (Currently Amended): A ~~composition~~ method as defined in claim 186, wherein the biologically active agent is an antigen.